

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC)
and Drug Safety & Risk Management Advisory Committee (DSaRM)
September 24, 2009

Draft Questions to the Committee

The following questions will be posed to the committee on September 24th:

- Discuss whether the studies performed by the sponsor adequately characterize the physical attributes of the reformulated OxyContin product.
 - Discuss whether the change in formulation affects the overall safety profile of OxyContin.
 - Should this application for a reformulated OxyContin should be approved. (Vote)
 - Discuss the rationale for your decision
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